

# Why do we need research and evidence for cannabis-based medicines?

There is increasing information available online and in the media about the use of cannabis in healthcare, and it can be difficult to separate fact from fiction



## What is research and evidence in healthcare?



Research is a carefully planned investigation of a topic, like a medicine or disease<sup>1</sup>



Through conducting research, such as randomised clinical studies, evidence is gathered to help determine if a medicine could be approved and used in patients<sup>2,3</sup>



For a medicine to be approved by a regulatory body, evidence from different preclinical and clinical studies is usually required<sup>4</sup>



All research needs ethical review and approval before a drug is approved as a medicine<sup>4</sup>

1

### Potential new medicine found<sup>4</sup>

- ↳ Does it have potential to help fight a specific condition or disease?

0 years<sup>5</sup>

3

### Clinical studies in healthy volunteers (Phase I) and a small number of patients (Phase II)<sup>4</sup>

- ↳ Is it likely to work?
- ↳ What are the side effects and what dose should be used?

+1–2 years<sup>5</sup>

5

### Approval as a medicine<sup>4–9</sup>

- ↳ A regulatory body, for example the FDA, EMA or MHRA,\* reviews the evidence gathered from research to determine if it is suitable for use in everyday medical practice
- ↳ Approval is always for a specific condition or disease

\*FDA = Food and Drug Administration; EMA = European Medicines Agency; MHRA = Medicines and Healthcare products Regulatory Agency

+1–2 years<sup>5</sup>

6

### Everyday medical practice<sup>4</sup>

- ↳ How well does the medicine work in everyday care?
- ↳ Are there any side effects when the medicine is used more widely?

2

### Animal (preclinical) studies<sup>4</sup>

- ↳ How does it work?
- ↳ Is it safe to start studying it in humans?

+1 year<sup>5</sup>

4

### Clinical studies (Phase III) in a larger number of patients<sup>4</sup>

- ↳ Does it work in patients?
- ↳ How well does it work?
- ↳ What are the side effects?

+2–3 years<sup>5</sup>

### Evidence-based healthcare<sup>2</sup>

The use of high-quality evidence to help doctors and patients make the right decisions about healthcare



High-quality evidence from research is essential for the approval of medicines

This is true for cannabis-based medicines as well as any other medicine



Learn more >

about what makes for high-quality evidence by visiting [www.cannabinoideducation360.com](http://www.cannabinoideducation360.com)

<sup>1</sup>FutureLearn. The concept of research. July 2021. Available at: <https://www.futurelearn.com/info/courses/global-issues-construction/0/steps/41405>. Accessed November 2021; <sup>2</sup>Masic et al. Acta Inform Med 2008;16:219–25; <sup>3</sup>BMJ Best Practice. What is EBM? July 2021. Available at: <https://bestpractice.bmj.com/info/toolkit/learn-ebm/what-is-ebm/>. Accessed November 2021; <sup>4</sup>Tamimi, Ellis. Nephron Clin Pract 2009;113:c125–31; <sup>5</sup>James Lind Institute. Clinical Trial Phases. September 2018. Available at: <https://www.jliedu.com/blog/clinical-trial-phases/>. Accessed November 2021; <sup>6</sup>Nursing Times. Why do I have to apply for ethical approval before I can begin my research? 2011. Available at: <https://www.nursingtimes.net/roles/clinical-research-nurses/q-why-do-i-have-to-apply-for-ethical-approval-before-i-can-begin-my-research-01-08-2011/>. Accessed November 2021; <sup>7</sup>FDA. 2021. Available at: <https://www.fda.gov/>. Accessed November 2021; <sup>8</sup>EMA. 2021. Available at: <https://www.ema.europa.eu/en>. Accessed November 2021; <sup>9</sup>MHRA. 2021. Available at: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>. Accessed November 2021



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